EndoSheath® Technology
Infection Control Considerations

The reasons to consider using EndoSheath® Technology rather than conventional flexible scopes requiring high level disinfection between uses are numerous. The material in this binder relates to minimising the risk of cross-infection.

The Vision Sciences flexible endoscopes do not incorporate a working channel. Instead, following a prescribed aseptic protocol, they are fitted with a disposable sterile sheath which incorporates the working channel. In this way the patient is not exposed to a contaminated surface.

The following pages comprise:

1) A leaflet explaining EndoSheath® Technology

2) Microbiological evaluation (cystoscopes)

3) Bronchoscope in a critical care unit

4) Aseptic EndoSheath technique (wall charts)

5) A comparison between "sterilised" cystoscopes and disposable sterile sheaths
Steve McCombie et al. (Norfolk & Norwich University Hospital) Journal of Clinical Urology Feb 2013

6) Outpatient Flexible cystoscopy using a disposable slide-on Endosheath system
M Kimuli, S Lloyd Ann R Coll Surg Eng, 2007: 89: 426-430

7) Microbiologic Assessment of Disposable Sterile Endoscopic Sheaths
Alvarado CJ et al Am J Infect Control 2009;37:408-13

8) Endoscope Sheaths as Viral Barriers: Laboratory FDA Study
Baker KH et al Laryngoscope 1999;109:636-9

9) Current limitations about the cleaning of luminal endoscopes
R.Herve, C.W. Keevil Jo of Hosp Infect 83 (2013) 22-29

10) Relevant points in CfPP 01-06 guidelines

11) Partial list of UK Endosheath users

Contact Genesis Medical for further information, a PowerPoint presentation on the Infection Control considerations, copies of referenced papers, a bibliography of relevant peer reviewed papers. Much material is available on the website: www.genmedhealth.com

November 2013

VISION sciences

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Infection Control
with EndoSheath® Endoscopy

EndoSheath® Technology

The sterile, disposable solution for flexible endoscopy

EndoSheath® Technology is not your typical barrier. Designed to offer a strong, durable, proven effective microbial barrier, this is not just a simple cover. By providing a barrier between the endoscope and patient, EndoSheath® Technology allows for less complicated cleaning and disinfection routines, and improves equipment turnaround time. All the difficult-to-clean endoscope components with EndoSheath® Technology are disposable, including: the barrier, the channels, the ports, and the seals. Clinically proven, EndoSheath® Technology allows for efficient, effective endoscope reprocessing in any setting.

With *EndoSheath® Technology* there is strength in numbers…

- **20+** years on the market
- **30+** FDA clearances
- **37+** systems with CE Mark
- **9+** systems with HealthCanada license
- **5+ million** procedures performed worldwide
- **0 cross-contamination complaints**

Reusable Endoscope

with sterile, disposable EndoSheath® Technology

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A name you can trust.

Pioneering Infection Control
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- EndoSheath® Technology is a proven effective barrier to organisms as small as 27 nanometers per FDA requirements and testing
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- Easy to use and prepare limiting the complexity of endoscopy preparation routines
- Compatible with standard accessories such biopsy forceps, needles, and other endoscopic devices
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- Disposables feature a 3-year shelf life
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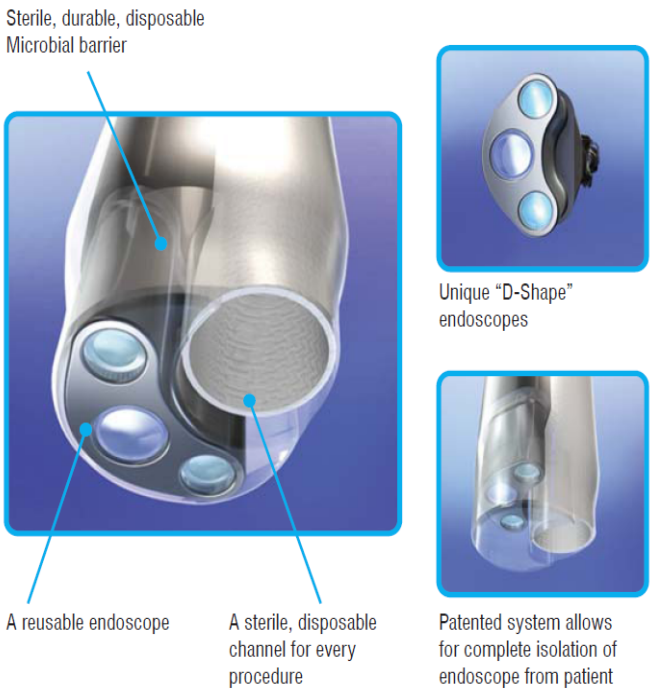
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Vision-Sciences,Inc. has brought pioneering concepts to the world of flexible endoscopy for over 20 years. With the patented EndoSheath® Technology and innovative endoscope designs, Vision-Sciences,Inc. has transformed the economics of flexible endoscopy while enhancing patient safety for Otolaryngology, Gastroenterology, Urology, and Pulmonology practitioners. Vision-Sciences has made a commitment to help physicians transform their practices with the EndoSheath® Technology.

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A microbiological evaluation of level of disinfection for flexible cystoscopes protected by disposable endosheaths

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A microbiological evaluation of level of disinfection for flexible cystoscopes protected by disposable endosheaths

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Abstract

Background

Flexible cystoscopy is used in urological outpatient departments for diagnostic cystoscopy of bladder cancer and requires a high-level disinfection between each patient. The purpose of this study was to make a microbiological post disinfection efficacy assessment of flexible cystoscopes (FC) using disposable sterile endosheaths.

Methods

One hundred endosheaths underwent a leak-test for barrier integrity after cystoscopy. Microbiological samples from these cystoscopies were obtained; after removal of the endosheath, and after cleaning the scope with a detergent cloth, rinsing with tap water followed by 70% ethanol disinfection and subsequent drying. The number of colony forming units (cfu) from the samples was counted after 72 hours and then divided in three categories, Clean FC (<5 cfu/sample), Critical FC (5–50 cfu/sample) and High-risk FC (>50 cfu/sample). The result was compared with data of 10 years continuous control sampling recorded in the

Copenhagen Clean-Endoscope Quality Control Database (CCQCD) and analyzed with a Chi-square test for homogeneity.

Results

All 100 endosheaths passed the leak-test. All samples showed a Clean FC and low means of cfu. A query to the CCQCD, showed that 99.8% (1264/1267) of all FC with a built-in work-channel reprocessed in a WD were clean before use.

Conclusion

The reprocessing of FC using endosheaths, as preformed in this study, provides a patient-ready procedure. The results display a reprocessing procedure with low risk of pathogen transmission, high patient safety and a valid alternative to the recommended high-level disinfection procedure of FC.

Keywords

Flexible cystoscopy, Endosheaths, Microbiological assessment, Disinfection, Bladder cancer

Background

Flexible cystoscopy is a common procedure in Danish urological outpatient departments (OPD). Based on the Danish Bladder Cancer Registry, up to 20 000 cystoscopies are performed each year for either diagnostic purposes or as part of post-surgery follow-up of bladder tumors (BT) [1]. FC can be classified as semi-critical or critical devices, and therefore a high-level disinfection between each patient has been suggested [2]. No general guidelines for reprocessing flexible endoscopes (FE) include FCs. The recommended standard disinfection of FCs consist of manual cleaning followed by rinsing and drying in a washer disinfector (WD) and finally flushing of the FC work-channel with alcohol . This practice is time-consuming as well as relatively expensive and requires specific equipment, facilities and trained staff. It is therefore of importance to develop and evaluate new approaches concerning this everyday urological procedure.

Studies on FCs with or without the use of disposable polymer endosheaths have been made. All have focused on optical quality, procedure time, patient comfort and financial aspects [3-6]. The present study is to our knowledge, the first to evaluate bacterial contamination of cystoscopes protected by endosheaths and the efficacy of reprocessing. Data on bacterial contamination in relation to level of disinfection are necessary where implementing new FC procedures in clinical use.

Methods

We included 100 patients who underwent flexible cystoscopy in the OPD, Frederiksberg Hospital, Denmark in the follow up of BT from August to December 2010. Only one cystoscope was used (Model CST_4000, Vision® Sciences, Inc.; Orangeburg, NY, USA)

covered by the sterile single use Slide-On Endosheath® System with the built-in work-channel in the endosheath (EndoSheath; Vision® Sciences Inc.; Orangeburg, NY, USA).

After cystoscopy, cultures were obtained immediately after removal of the sheath, using sterile saline pledgets (Sterile Wipes PDI®, Inc. Orangeburg, NY, US), from the maneuver part and the insertion part of the cystoscope, as described by Alvarado et al [7]. Then, the cystoscope was wiped with a detergent cloth (Wet Wipe® A/S; Vallensbæk, Denmark), rinsed with running tap water, manually dried off with gauze, wiped with 70% ethanol soaked gauze and finally hung vertically for the ethanol to evaporate. Post disinfection cultures were also obtained, after 10 minutes drying.

The sample pledgets were placed in 1 ml sterile saline and shaken for 30 seconds. Ten drops of 0.02 ml aliquots from the sample were spotted on two 5% blood agar plates (Statens Serum Institut, Denmark) and incubated at 35°C in CO^2. The total number of colony forming units (cfu) was counted after 72 hours. Bacteria were speciated using standard methods.

The endoscope was visually inspected after use for contamination with body fluids. All 100 sheaths underwent a test for barrier integrity post cystoscopy using a Leak Testing/Pressure Decay Equipment (Vision® Sciences Inc., Orangeburg, NY, USA).

After sampling the cystoscope was reprocessed according to standard operating procedures in a WD.

As in the Copenhagen Clean-Endoscope Quality Control Database (CCQCD) we defined three grading levels of reprocessing FC. Clean FE (<5 cfu/sample), Critical FE (5–50 cfu/sample) and High-risk FE (>50 cfu/sample).

The disinfection quality level of FC after traditional reprocessing and FC with sterile endosheaths with a built-in work-channel were compared.

The results of samples obtained before and after reprocessing the FC were analyzed for homogeneity with a Chi-square test, based on means of cfu.

The study was performed in accord to the Helsinki Declaration and regulations of the local ethical committee and was regarded as a quality performance project and all patients participating in the procedures, were adults and had given their oral and written accept.

Results

All samples obtained after removal of the sheath and after cleaning and alcohol disinfection, both from the maneuver part and insertion part of the FC showed a Clean FC with a mean of 0.2 cfus (Table 1). Table 1 shows that, samples from the FC before and after reprocessing demonstrated no significant reduction of cfus by reprocessing. The bacteria identified were coagulase negative staphylococci, Bacillus species and Corynebacterium species.

Table 1 Microbiological samples from 100 cystoscopies preformed with a Vision Sciences FC (Model CST 4000; Vision® Sciences, Inc.), after removal of the endosheath and after cleaning the FC with a detergent cloth, rinsing with tap water followed by 70% ethanol disinfection and subsequent drying

				Maneuver part	Insertion tube
		ARS	AD	ARS	AD
No. of samples		100	100	100	100
No. of cfu/sample					
Clean FC	0	82	87	88	87
	1	12	11	9	9
	2	4	1	3	3
	3	2	1	0	0
	4	0	0	0	1
High-risk/Critical FC	>5	0	0	0	0
Mean cfu/sample (NS)		0.26	0.16	0.15	0.19

ARS After removal of the sheath, *AD* After disinfection, *NS* Non-significant.

All 100 endosheaths passed the leak-test after the cystoscopy and no endoscopes were visibly contaminated with body fluids.

A query to the CCQCD, showed that 99.8% (1264/1267) of all FC with a built-in work-channel reprocessed in a WD were clean before use.

Discussion

After using FCs with disposable sterile endosheaths, the ensuing cleaning and disinfection of the FCs serves two purposes. The first is to clean the endoscope in case of failure of antiseptic technique by the user. The second is to mechanically remove material that may have been deposited by the insertion tube or onto the scope while applying or removing the sheath.

The use of endosheaths in this study ensured that no body fluids came in contact with the scope, making it possible to do the manual cleaning with a pre-packed single use cloth, moistened with a non-enzymatic detergent in the examination room.

Prevention of contamination with bacteria from the patient and environment is reliably prevented with 70% ethanol. Furthermore 70% ethanol protects against most viruses (except, for instance HPV) and evaporates water leaving the FC dry. Being dry before reuse, it is now possible to do a "leak test" by inspecting the scope-surface for moisture after removal of the next sheath. If the surface of the FC was wet after removal of the endosheath, it could indicate a leak and that direct contact between mucosa and cystoscope had taken place.

The few bacteria (1 to 4 cfus) we identified originated from skin commensals, and were found in a few samples taken both before and after reprocessing the FC. As no leak was detected, the contamination is presumed to come from the handling of the FC or from sampling procedures.

A study by Alvarado et al. [7] showed clean flexible nasopharyngoscopes (FN) after they were desheathed and cleaned with enzymatic detergent followed by 70% ethanol disinfection

and evaporation. They developed the method used in our study, and even though a FC is longer than a FN, we only found a few cases of contamination with the same environmental microorganisms. This indicates that our method of reprocessing the FC, without the use of enzymatic detergent, was reliable. Should a leak occur, it will be revealed by the presence moisture on the FC after removal of the sheath. This contaminated FC, which had contact with body, must be processed by manual cleaning with an enzymatic detergent followed by a high level disinfection in a washer desinfector [2,8]. This setting requires a separate cleaning room with a basin with a detergent solution to soak and manual clean the FC.

The quality of the disposable sheaths used was high. In a prior study with 875 endoscopic procedures, no leak has been reported [7]. We used sheaths approved by the USA FDA, that are resistant to microorganisms as small as 27 nm and are made out of material with high integrity, unlikely to tear or leak, in contrary to other commonly clinically used barriers [9]. An evaluation of sheaths as a viral barrier has shown a low risk of viruses from contaminated scopes penetrating micro holes and tears in the sheath [10].

The risk of a urinary tract infection (UTI) after FC is estimated to be < 2% to 7.5% [3]. Diagnosing UTI in relation with FC can be difficult due to hematuria, urge, dysuria and leucocyturia, all symptoms that can occur with or without the presence of bacteriuria. In the reported cases of UTIs found in relations with FCs, it has primarily been endogenous bacteria, presumably the patient's own microorganisms [11].

Exogenous FC related infections appear to be very rare in cystoscopy. Only two major outbreaks have been reported, with UTIs caused by Pseudomonas aeruginosa as a consequence of insufficient reprocessing of the FC. Other studies have showed a correlation between outbreaks and previously damaged or poorly decontaminated instruments [12].

Current USA Multisociety Guideline on Reprocessing Flexible GI Endoscopes, 2011, does not address reprocessing of FCs and FBs [8].In Denmark only automatic decontamination in a WD is recommended when reprocessing FE. Compiled data from the CCQCD has shown a constant low risk of contaminated FC, after manual cleaning including brushing of the work-channel followed by a high level disinfection in an automatic WD. This suggests a differentiation of the guidelines of reprocessing FEs. In comparison with other types of endoscopes, the decontamination of FCs is less complicated because they are single channel instruments. When using FCs with endosheaths, the work-channel is placed in the sheath and the endoscope will generally only become contaminated from handling.

This study did not look into optical quality or patient comfort. In a retrospective overview of the post procedure descriptions and when asking the urologist who performed the cystoscopies, poor optical quality and handling problems were mentioned. Our general impression was that the sheaths slightly reduced vision and resulted in some discomfort for the patients as compared to FC without sheaths. A recent published trial by Krebs et al. assigned 97 patients in a control group with unsheathed FC and a group undergoing sheathed FC (EndoSheath System). The Sheathed procedure saved between four to 31 minutes of reprocessing time, while avoiding exposure to irritants found in conventional soaking methods. The control group scored better than sheath group regarding to insertion of FC, general handling and rinse-water setup ($P \leq 0, 01$). No significant difference was found between the two groups comparing procedure time, optical quality and patient comfort both before and after the procedure [4]. Three non-comparative studies reported a minor

disadvantage in sheathed FC concerning handling and set up [4-6]. The process of applying and removing the sheath on the FC took approximately one to two minutes.

The current marked prize in Denmark is about $49 per sheath (2012), but most OPDs would be required to change their FCs to FCs compatible with an endosheath system. Nevertheless, when looking at the economical aspect of using sheaths for FCs, the cost of high level disinfecting and staff performing manual cleaning must be considered in the equation [4].

Conclusion

The reprocessing of FC using endosheaths, as preformed in this study, provides a patient-ready procedure. The results display a reprocessing procedure with low risk of pathogen transmission, high patient safety and a valid alternative to the recommended high-level disinfection procedure of FC. However, the general impression was that sheaths slightly reduced vision and resulted in some patient discomfort.

Competing interests

The Foundation Juchum and the Boemske Foundations have provided financial support for this study.

Authors' contributions

PHJ is first author on the article and has been instrumental in the connection of the urological and microbiological parts of the study as well as being involved in the clinical execution of the flexible cystoscopies. TS is responsible for the conception and design of the study, acquisition of data, analysis of data as well as drafting the primary manuscript. TW has been an important key person behind intellectual content of the microbiological part and critically reviewer of the final draft of the manuscript. VB has been involved is the practical setup and execution of the study. She has been clinical involved in the flexible cystoscopies and collection of data. GGH is responsible for the intellectual content of the urological part of the study as well being the connecting and coordinating person throughout the process. He has given final approval of this version to be published. All authors read and approved the final manuscript.

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EndoSheath-Technology: A new always ready, always sterile flexible bronchoscope. A preliminary evaluation in Critical Care Unit

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Bronchoscope-associated pneumonia can be caused by the improper use of the disinfection process. High-level disinfection is time-consuming. The single-use EndoSheath-Technology is designed to isolate the bronchoscope from contact with the patient and provides a instrument always ready, always sterile.

Objective: To examine the impact of the EndoSheath-Technology on reducing the bacterial contamination of the bronchoscopes and obviating the need of routine high-level disinfection in reprocessing; to measure overall performance of the device.

Methods: The bronchoscope was not so widely adopted in critical care units. In our ICU it was tested from June 2012 to June 2013. The device was cultured before the application of the protective sheath; after the procedure and removal of the sheath and after enzymatic cleaning, drying and disinfection with 70% ethanol. A sterile pledget was wiped on the entire surface of the insertion tube and a second one on the entire surface of the control head. Both were placed in sterile specimen containers for culture. After each procedure, the bronchoscopist rated the performance of the device using a semi-quantitative linear score (0=minimum; 5=maximum).

Results: Fifty-three procedures were performed in twelve months.

The procedures consisted of: nineteen BAS; thirty-one BALs; three PCT.

The procedures were steriles; two (3.8%) turned out positive for CoNS or Sphingomonas paucimobilis. Both of these results were contaminated on purpose by an operator touching several areas and other devices in the ICU.

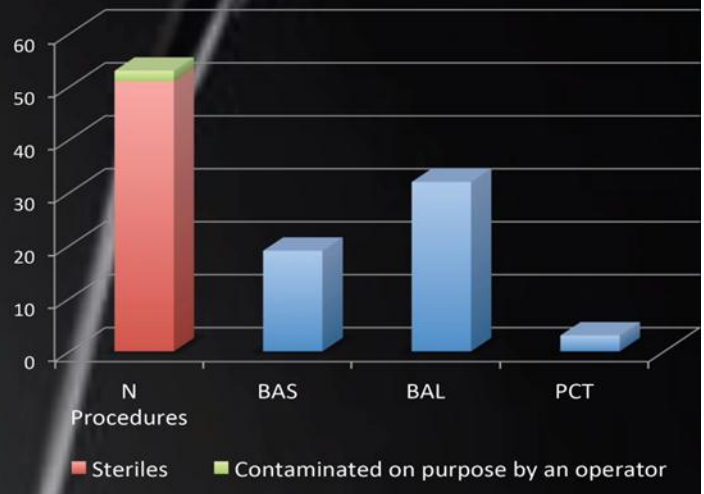
The device was judged positively for perfomance in terms of visualization (defined by clarity of the image and brightness), suitability (defined by general comfort and easiness of use) and function usefulness (defined by potency of aspiration and injection, tip movements).

Mean "visualization score" was 3.9 (95% CI: 2.2-5.6)

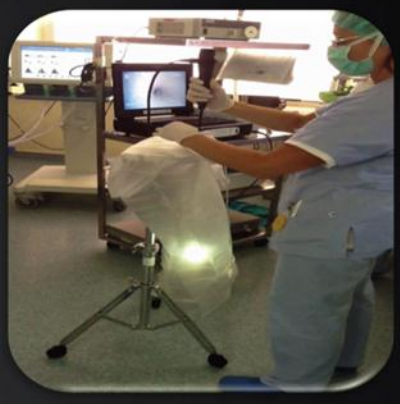
Mean "suitability score" was 3.0 (95% CI: 1.6-4.4)

Mean "function usefulness score was 3.1 (95% CI: 1.7-4.5)

The operator's experience (defined using a score 1: fellow; 2: attending physician) had no influence on the performance of the device. The following table shows the relative univariate analysis (Student's t-test).



	Mean visualization	Mean suitability	Mean function
Fellows	4.2 ± 1	3.2 ± 1	3.1 ± 1
Attendings	3.8 ± 0.8	2.9 ± 0.6	3.1 ± 0.7
p	0.31	0.27	0.98



Conclusion: The EndoSheath-Technology seems to have the potential to reduce the downtime between bronchoscopies by eliminating need of high-level disinfection between procedures, the nursing team is no longer exposed to noxious disinfectants. The performance is satisfying even if some improvement could be suggested and the comparative study will confirm the first data on reduction bacterial contamination.

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Vision Sciences Endoscopes and EndoSheath ® Technology Preparation Wall Chart

PRECAUTIONS:

- Endoscopes and EndoSheath® Technology should not be used without a thorough review and understanding of the User's Manual.
- Before inserting the Endoscope into the Sheath, ensure that the insertion Tube is Clean, Dry and Undamaged.
- Review the User's Manual for Recommended Cleaning procedures for the Endoscope.
- If setting up for sterile field, double-glove with sterile gloves.

BEFORE THE PROCEDURE - SET UP

STEP 1

Carefully place Sheath contents in sterile field.

STEP 2

Double glove, Sterile. Apply drape bag to installation stand

STEP 3

Place Sheath into installation stand with accessory port facing out

STEP 4

Gently insert Scope into Sheath with the endoscope label facing forward and the flat edge of the insertion tube against the flat edge of the Sheath connector opening

IMPORTANT NOTE

The tip of the scope MUST be straight when placing into Sheath. If there is any resistance in loading, verify that the Sheath channel is properly aligned. If the channel is misaligned / twisted, straighten the channel before continuing scope insertion

STEP 5

Lock Sheath to Scope by turning knob 90⁰ (horizontal)

STEP 6

Deflect Scope tip to ensure Sheath window is seated properly.

STEP 7

When applicable insert irrigation/suction tube through the flow control valve.

STEP 8

Attach the end of the irrigation/suction tube to an irrigation/ suction source.

IMPORTANT NOTE

When using a CV-1.5 Sheath, attach the irrigation source tubing directly to the sheath connector accessory port.

STEP 9

If setting up sterile, remove outer gloves. Unfold cover over control body of Scope and secure with clips.

STEP 10

Ready for use. Verify angulation function and water flow/suction before use.

AFTER THE PROCEDURE - REMOVAL

STEP 11

Double glove before starting removal process. Re-insert Scope into stand, detach clips and move control Body Cover without contaminating handle. Remove outer gloves.

STEP 12

Detach irrigation/ suction Tube from the Flow Control Vale and Water Source.

STEP 13

Unlock Sheath rom Scope by Turning the Locking Knob to the Vertical Position.

STEP 14

Remove Scope from Sheath.

IMPORTANT NOTE

If resistance is felt during removal. STOP, Make sure the sheath and Scope are STRAIGHT and ensure the channel is not wrapped around the insertion tube. Use the drape bag as a barrier between the fingers and sheath, gently grasp the window of the Sheath and remove the Scope WITHOUT rotating the Scope

STEP 15

Deposit used Sheath and gloves into drape bag and dispose as per hospital policy.

EndoSheath® Technology

VISION® sciences

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genesis ENDOSCOPY

for innovation, for reliability, for peace of mind

Endoscope with EndoSheath® Technology

Reprocessing Chart for Recommended Cleaning Procedure

The EndoSheath® Technology is a sterile, disposable, durable protective barrier which isolates an endoscope from patient contact, and limits the need for elaborate chemical disinfection or EtO sterilization procedures after every endoscopy procedure. EndoSheath® Technology allows for fast and effective reprocessing of an endoscope and ensures a sterile Insertion Tube for every patient.

IMPORTANT NOTES:

1. Users should review complete manufacturer's guidelines for equipment disinfection/sterilization found in the user's manual.
2. Users should review EndoSheath® Technology installation/removal process found in the user's manual.

WARNING: This chart is only for reprocessing of Vision Sciences® endoscopes using EndoSheath® Technology

Remove endoscope from Sheath and place in a clean/Sterile area. Do not handle the endoscope with contaminated gloves

After removing the Sheath, Inspect the endoscope insertion tube and distal bending section and confirm these areas are dry and undamaged.

NOTE

If the endoscope was dry when the sheath was fitted it will be dry when removed. If moisture is observed, this could indicate a breach of the sheath and high level disinfection can be considered. If high level disinfection is decided upon, the endoscope must be prepared according to instructions in the user manual.

CLEANING AND INTERMEDIATE LEVEL DISINFECTION

Gently wash all external surfaces of the endoscope with an appropriate instrument grade detergent or EndoWipe™ Enzymatic sponge

After washing thoroughly rinse the outside of the Endoscope with clean lukewarm water.

Wipe down the entire Endoscope with Gauze soaked in 70% ethyl/isopropyl alcohol or an EndoWipe™ Towelette . Ensure full coverage of alcohol

Ensure all external surfaces of the Endoscope are dry prior to installing another Sheath.

LEAK TESTING (if chemical immersion is necessary)

Connect the leak tester to the endoscope's EtO/vent valve. Push down and rotate the leak tester connector clockwise until it is secured.

Pressurise the Endoscope. Ensure leak tester's valve is closed. Pump the hand bulb until the needle reaches the green section. Maintain pressure for 10 seconds, observing the needle position. Endoscope may require several pumps of the bulb to completely pressurise

If the needle position remains steady. Immerse the entire scope in water and observe if for 30 seconds. Angulate the distal bending section up and down while the Endoscope is immersed. The absence of air bubbles confirms the scope is air tight. Remove from water and open the leak tester's valve. Ensure the needle on the pressure gauge fails to zero and disconnect the leak tester from the endoscope.

NOTE

If the pressure decreases the leak tester connection may be loose or the pressure valve on the leak tester may be open Re-attach the leak tester. If the symptoms persists, contact Genesis Medical. A small stream of bubbles indicates a leak in the endoscope that was not detected by pressure gauge. Do not continue to use a leaking endoscope and contact Genesis Medical for repair.

EndoSheath® Technology

In the event that high level disinfection/sterilization is required, please refer to the protocols in the user's manual for proper steps to ensure complete and efficacious reprocessing.

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Journal of Clinical Urology **February 25, 2013**

Urinary tract infection following flexible cystoscopy: a comparison between sterilised cystoscopes and disposable sterile sheaths

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Abstract

Objective: The objective of this article is to compare the incidence of post-cystoscopy urinary tract infections (UTIs) between cystoscopes sterilised between patients and cystoscopes that use removable sterile sheath technology.

Patients and methods: A total of 200 patients undergoing flexible cystoscopy at the Norfolk and Norwich Hospital (Norwich, UK) between November 2011 and March 2012 were identified prospectively as part of an ongoing audit of the department's services. One hundred patients were recruited from day procedure lists, using KeyMed® cystoscopes sterilised between patients (sterilised scope, SS); 100 patients were recruited from a 'one-stop' urology clinic, using a Vision Sciences® CST-5000 cystoscope with disposable sterile Endosheath® technology (removable sheath, RS). Mid-stream urine (MSUs) samples and patient symptoms were recorded prior to the cystoscopy and at least three days following the cystoscopy.

Results: No significant difference was found in the incidence of new MSU-confirmed UTI (2.7% (SS) vs. 2.0% (RS)). In those undergoing their first cystoscopy, no significant differences were found in either new symptoms (34.1% (SS) vs. 36.7% (RS)) or requirement for antibiotics (13.6% (SS) vs. 13.0% (RS)).

Conclusion: Flexible cystoscopy using removable sterile sheath technology does not have a higher incidence of UTI compared to a cystoscope sterilised between patients. The introduction of cystoscopes using this technology can therefore safely transform flexible cystoscopy into an outpatient clinic procedure.

Acknowledgements
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Conflict of interest
The authors declare that there are no conflicts of interest.

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Out-patient flexible cystoscopy using a disposable slide-on™ endosheath system

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ABSTRACT

INTRODUCTION The aim of this study was to investigate the feasibility of out-patient flexible cystoscopy.

PATIENTS AND METHODS Twenty-seven patients awaiting diagnostic or check cystoscopy in Leeds, UK were invited to undergo out-patient flexible cystoscopy using a CST-2000 Flexible Cystoscope (Vision Sciences; Natick, MA, USA) using the sterile single-use slide-on™ disposable endosheath endoscope system (EndoSheath®; Vision Sciences). The performance of the cystoscope was evaluated, and the patients' experiences were documented using a questionnaire.

RESULTS The out-patient setting proved to be ideal for flexible cystoscopy. The cystoscope was rated highly for image quality, ease of use and handling. All patients complimented us on the service and preferred out-patients to a day-ward or theatre attendance.

CONCLUSIONS This study demonstrates that it is possible to perform out-patient flexible cystoscopy safely, economically and efficiently with the aid of a disposable endoscope system.

KEYWORDS

Flexible cystoscopy – Vision Sciences – Disposable endoscopy sheaths – Slide-on™ endosheath system

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Flexible cystoscopy is the most frequently performed urological procedure both as a diagnostic and surveillance tool. Freely available facilities to flexible cystoscopy is fundamental to modern urological practice but this is often limited by access to facilities, sterilisation and instrumentation resulting in significant waiting times for the procedure delaying diagnosis and treatment. Most units perform flexible cystoscopy in a day-ward theatre setting, others in purpose-built endoscopy units, few in the out-patient setting. Within our unit, flexible cystoscopy is performed in day-ward theatres, waiting times for non-urgent flexible cystoscopy has reached 9 months. Purchasing and servicing a large number of instruments was considered costly. Moving flexible cystoscopy into an out-patient setting with the implementation of the new Vision Sciences flexible cystoscope using slide-on™ endosheath system may overcome these difficulties and provide an opportunity to improve efficiency.

This paper reports our initial experience with this new device comparing it with standard flexible cystoscopy in an out-patient setting.

Patients and Methods

Twenty-seven patients on the day-case waiting list for diagnostic flexible cystoscopy were randomly chosen to be part of the pilot for the out-patient flexible cystoscopy list. Initially, small numbers were listed to establish the processes; the last list accommodated 10 patients comfortably. All patients were given an information sheet in the waiting area prior to the procedure. They were interviewed using a simplified assessment sheet and consented by the operator (Appendix 1). Patients did not fully change as in the day-ward setting but removed their lower half garments in the treatment room behind a screen.

The Vision Science CST-2000 flexible cystoscopy was used for all procedures. At first glance, the flexible cystoscope looks similar to existing instruments but closer inspection reveals several key differences (Fig. 1A–D). The cross-section of the instrument is crescenteric and measures 13.8-F by 16.8-F. It has a lever to lock onto the disposable sheath and a depression valve for irrigation. The sheath incorporates a 6-F working channel for biopsy and ureteric stent removal.

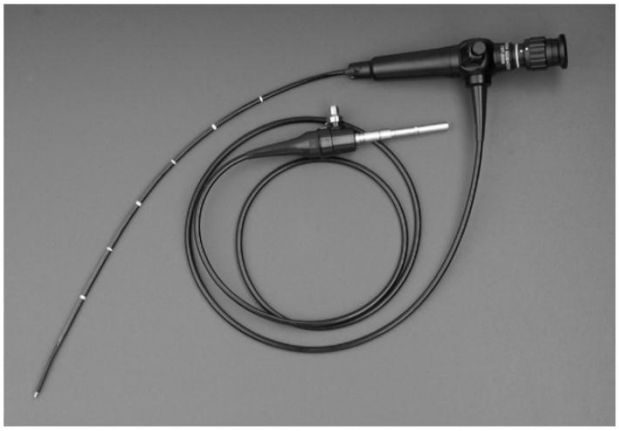

Figure 1 CST-2000 Flexible cystoscope with the sterile, single-use slide-on disposable endosheath.

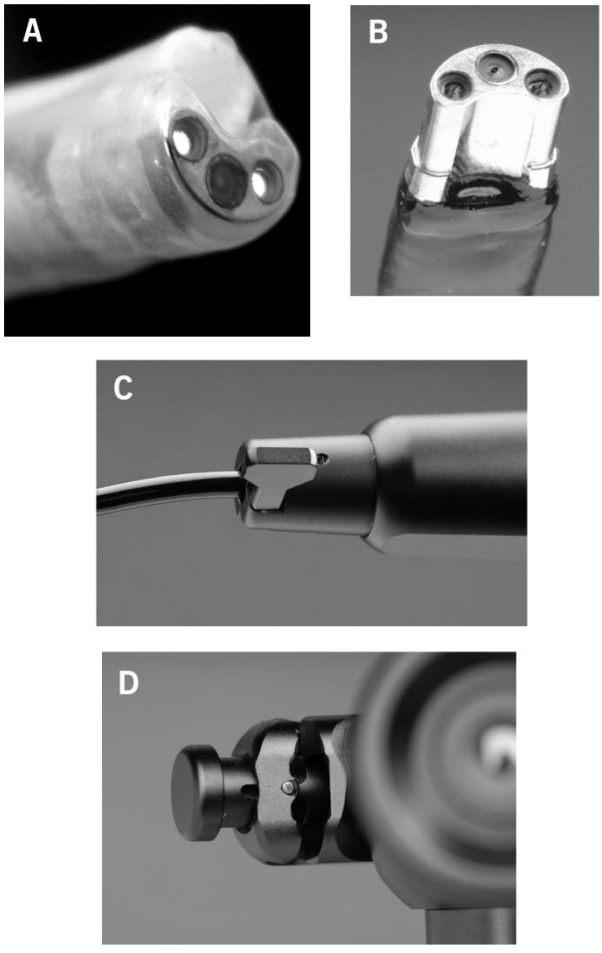

Figure 2 Crescent-shaped flexible cystoscope with (A) or without (B) an endosheath. (C) The lever that locks the cystoscope into the sheath. (D) The irrigation valve.

The cystoscope is sterilised at the beginning and end of the list with conventional techniques using peracetic acid. The single-use, slide-on sheath is employed between each patient. For each procedure, both the operator and the assistant wear double-layer, sterile gloves so as not to contaminate the instrument when re-sheathing. At the beginning of each procedure, the individually pre-packaged sheath is secured on a table-top fixed device. The instrument is inserted into the sheath and the two are locked together with a catch on the instrument (Fig. 2A–D). The sheath is pulled over to cover the rest of the cystoscope before attaching a camera. The instrument is introduced into the urethra in a standard fashion after cleaning and insertion of local anaesthetic jelly. At the end of the procedure, the assistant slides the sheath off the instrument, removes the outer gloves and inserts a new sterile sheath into the table-top holding device. The operator inserts the cystoscope into the new sheath, removes the outer gloves before pulling the sheath onto the rest of the instrument. The cystoscope is now ready for the next patient. The de-sheathing and re-sheathing process takes about 2 min. A standard catheterisation pack was used to provide the swabs and paper towel.

The assessment of the procedures was evaluated according to ease of use, flexibility and vision. Staffing ratios and patient flows were developed as the clinic progressed until the ideal levels were identified. The patients were asked to give feedback of the out-patient cystoscopy service.

Results

Out-patient setting

The out-patient setting proved to be ideal for flexible cystoscopy utilising a treatment room used for catheterisation and the main waiting area as pre-waiting and recovery area. The optimum staffing ratios were a receptionist, one trained (assistant) and one untrained nurse and the operator.

Instrumentation

EASE OF USE

Once the operator and assistant became familiar with the sheathing, the whole process of sheathing and re-sheathing became smooth and efficient. The whole process was more intricate than normal but the benefits outweighed the disadvantages. Care was taken not to put the instrument down after use until it was re-sheathed ready for use again. On four occasions, the sheath clung to the scope due to friction requiring the sheath to be cut off. Finally, there was no break in the integrity of the sheaths or damage to the instrument.

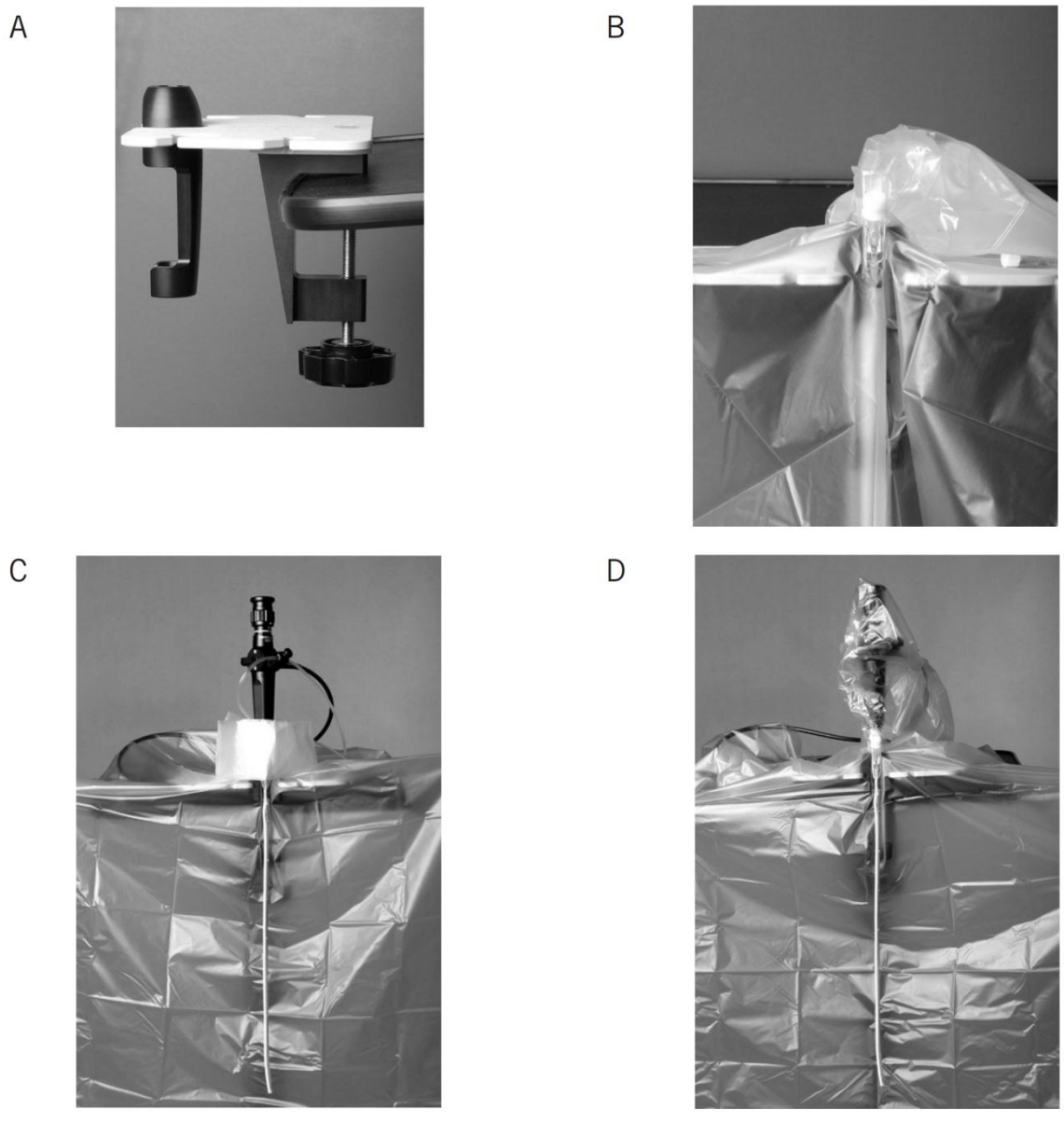

Figure 3 The installation stand attached onto a table (A) before securing the endosheath (B). The distal end of the cystoscope is inserted into the opening of the sheath (C) while the eye-piece is covered by the remainder of the sheath (D).

FLEXIBILITY

The instrument handled identically to conventional scopes with no restriction of movement (Fig. 3) or handling. The instrument is lighter than most, which is a distinct advantage when the camera was attached to the eyepiece. The working channel allowed passage of a biopsy forceps which, in one patient, facilitated retrieval of a foreign body (Fig. 4).

OPTICS

There was no noticeable reduction in quality of vision by looking through the transparent tip at the end of the scope.

Patient feedback

All patients complimented us on the service and preferred to come to out-patients rather than attend day-ward or day-theatre. They did have higher expectations of attending for

Figure 4 A foreign body retrieved from a patient.

an appointment whereas day-theatre patients seem to accept a longer wait for their procedure.

Discussion

Out-patient flexible cystoscopy is not a new concept but this requires either support with sterilisation units or several pre-packed scopes, which may limit the number of procedures that could be performed. The use of the re-sheathable, flexible cystoscopy overcomes most of these obstacles, potentially freeing up valuable day-theatre or endoscopy theatre time.

Vision Science also manufacture disposable sheaths for ENT instrumentation which have found favour in many centres including our own.[1] The disposable nasopharyngo-laryngoscopy sheath has proven cost-effective and has resulted in large numbers of procedures being performed in the community setting rather than in secondary care.

The US FDA-approved sheath is a proven effective barrier to micro-organisms as small as 27 nm (equivalent to a polio virus particle size) and is designed to isolate the patient from the cystoscope. Current, high-level disinfection of flexible cystoscopes uses either glutaraldehyde or peracetic acid. The efficacy of glutaraldehyde relies on 'meticulous', manual pre-cleaning. although symptomatic iatrogenic infection rates are low, this is likely to be due to under-reporting[2] as previous studies have shown a 15—17% positive culture rate in 'patient-ready' scopes.[3,4] Though more effective, peracetic acid disinfection is equally time-consuming, labour-intensive and, potentially, a costly process.[5] There have been scares about cross-contamination between patients undergoing endoscopies. Three-thousand patients had to be contacted recently due to problems with decontamination.[6]

Out-patient flexible cystoscopy is not a new concept. Each urology unit provides flexible cystoscopy in differing facilities with varying numbers of instruments and staffing levels. In Leeds, all flexible cystoscopies are performed within the day-theatre setting in four different hospitals with a total of eight lists per week. Transportation is needed before and after each list to move instruments around the city as well as the staff. This initiative has proven that all such lists could be moved into an out-patient setting. The cost of the Vision Science flexible cystoscopy is less than standard instrumentation; the cost of the disposable sheaths is £18 + VAT each from Dantec Dynamics Ltd.

All patients in our study preferred out-patient rather than day-case attendance. The next step would be to offer flexible cystoscopy at the time of out-patient attendance eliminating waiting times which can only improve the outcome of care. The flexible cystoscope could be pre-sterilised and ready for use; once used, it could be available for subsequent patients. This process could avoid costly instillations of sterilising equipment. These lists were carried out in a treatment room in the out-patient department adjacent to the day-theatre. There was no significant impact on the sterilising turnover of the existing endoscopy lists in this unit.

Conclusions

We would commend urologists and managers to consider the investment in out-patient flexible cystoscopy provision for both diagnostic and surveillance endoscopy and that the Vision Science CST-2000 with slide-on™ endosheath system be part of the planning.

Acknowledgement

The authors have no financial involvement or interest with Dantec Dynamics Ltd, Garonor Way, Royal Portbury, Bristol BS20 7XE, UK.

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APPENDIX 1

The simplified assessment sheet used to assess patients before undergoing cystoscopy

Leeds Teaching Hospitals NHS Trust Flexible Cystoscopy

Date of admission ----------

Name (addressograph)

Next of kin/carer ----------

Contact No ---- ----------

GP ---------- ----------

Transport home: Car, taxi, bus, ambulance. Accompanied or self

PAST MEDICAL HISTORY

Heart disease, Heart murmur --- Yes/No

Diabetes ---------- Yes/No

Possibility of pregnancy ------- Yes/No

MEDICATION

Warfarin ----------Yes/No

Antibiotics ----------Yes/No

Allergies to drugs, antibiotics, latex, *etc.* ---Yes/No

URINALYSIS

Protein ---------- Yes/No

Blood -------Yes/No

INFORMATION FOR CONSENT

Verbal/written ---------- Yes/No

PRE-OPERATIVE CHECK:

Signature ----------

Identity band applied ----------

Allergies noted ----------

Relevant blood results present ----------

Urine tested ---------- Pulse ------ BP ---/ ---

OPERATIVE PROCEDURE ----------

STERILISATION TRACKING

DISCHARGE CRITERIA

Passes urine — Clear/blood-stained

Has had something to eat/drink — Yes/No

GP discharge letter and information given Yes/No — Time of discharge

Print name of nurse ---------- **Signature of nurse** ----------

Microbiologic Assessment of Disposable Sterile Endoscopic Sheaths: Prospective Clinical Trial

Alvarado CJ, Anderson AG, Maki DG. Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: a prospective clinical trial with nasopharyngoscopes. *Am J Infect Control* 2009;37:408-13.

In this article, Alvarado et al described a clinical trial that included a microbiologic assessment of the ability of the Slide-On® EndoSheath® Technology (Medtronic ENT, Jacksonville, FL) to provide protection against bacterial contamination of flexible nasopharyngoscopes. Three 30-mm Olympus nasopharyngoscopes (ENF Type P4, Olympus America, Melville, NY) were used while covered with an EndoSheath® barrier to examine the nasopharynx and larynx of 100 different, randomly selected patients. The surface of the head and shaft of each nasopharyngoscope was wiped to obtain two samples for culture at each of the following times: before application of the EndoSheath® Technology and the endoscopic examination, immediately after the examination and removal of the EndoSheath® disposable, and after a disinfection procedure consisting of the following steps: vigorous wiping of the endoscope with an enzymatic detergent, rinsing with running tap water, drying with gauze, wiping with gauze soaked in 70% ethanol, and air drying in a vertical position. All samples were plated on 5% sheep blood agar and incubated for 72 hours at 37°. Bacterial colony types were enumerated and identified by using standard methods. The study also included leak testing of the 100 used disposable sheaths removed from the nasopharyngoscopes and of 20 unused sheaths taken from the clinic inventory. The barrier integrity of the EndoSheath® Technology was assessed by using a pressure decay system (138 ± 2 inches of water [5 lb per square inch]).

Bacteria grew in cultures of 16 head and 6 shaft samples obtained before the endoscopic procedure, 13 head samples and 1 shaft sample taken immediately afterward, and no samples obtained after the disinfection procedure. The contamination found was low level (2 to 100 colony-forming units) and due primarily to skin commensals, mainly coagulase-negative *Staphylococcus* and *Bacillus* species. One sample was positive for *Staphylococcus aureus*; none showed gram-negative bacilli or fungi. None of the 120 used or new sheaths lost barrier integrity on leak testing. Alvarado et al noted that not a single leak or tear had been detected in the total of 755 sheaths in their study and all previously reported clinical trials in which the EndoSheath® Technology was used.

In light of their findings, the researchers concluded that use of the EndoSheath® Technology followed by proper cleaning and intermediate disinfection with 70% ethanol can provide a safe, patient-ready nasopharyngoscope, with reliable protection against contamination by virulent bacteria pathogens such as methicillin-resistant *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and mycobacteria species and by viruses likely to be present in the respiratory tract. Alvarado et al also suggested that the acquisition costs of disposable sheaths would be offset by avoidance of high-level reprocessing of flexible endoscopes, which is expensive and may expose health care workers to toxic disinfectants; by reductions in endoscope downtime; and, possibly, by a decrease in costs associated with inadequate high-level reprocessing practices.

Endoscope Sheaths as Viral Barriers: Laboratory FDA Study

Baker KH, Chaput MP, Clavet CR, Varney GW, To TM, Lytle CD. Evaluation of endoscope sheaths as viral barriers. *Laryngoscope* 1999;109:636-9.

The aim of this bench study conducted by scientists at the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA) was to characterize virus transmission through otolaryngologic endoscope sheaths in which a hole or tear had been made with an excimer laser or acupuncture needle. EndoSheath® Technology (n = 22) with a hole or tear ranging from 2 to 84 µm were applied to an endoscope, which was then submerged in a high-titer virus suspension (108 viruses/mL). The inside of each EndoSheath® barrier and the endoscope on which it had been placed were then rinsed separately to determine the amount of any virus that had penetrated through the hole.

A sequential test was also conducted. In this experiment, a virus challenge was first performed outside an EndoSheath® disposable in which a 30-µm hole was created before it was applied to an endoscope. The EndoSheath® Technology was then removed from the possibly contaminated endoscope, and a second EndoSheath® barrier, in which a 20-µm hole had been made in the same location as the 30-µm hole in the first EndoSheath® disposable, was placed on the endoscope. Another virus challenge was conducted to determine whether any virus would pass outward through the second sheath.

The first experiment found that small volumes of virus-containing fluid penetrated through the holes or tears in the EndoSheath® Technology and that up to 45% of passed virus particles could be recovered from the endoscope after removal of the EndoSheath® Technology. In the sequential test, virus was found on the second disposable barrier in only one case. Most important, according to the researchers, no virus was found outside the second sheath.

The FDA researchers recommended that an endoscope reprocessing step be combined with use of disposable sheaths. They also said, however, that their data indicated that the step need not be high-level disinfection. Instead, they concluded that meticulous cleaning of an endoscope followed by intermediate-level disinfection should provide a safe instrument for otolaryngologic endoscopy.

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Current limitations about the cleaning of luminal endoscopes

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Luminal endoscope
Decontamination
Prion
CJD

SUMMARY

Background: The presence and potential build-up of patient material such as proteins in endoscope lumens can have significant implications, including toxic reactions, device damage, inadequate disinfection/sterilization, increased risk of biofilm development and potential transmission of pathogens.

Aim: To evaluate potential protein deposition and removal in the channels of flexible luminal endoscopes during a simple contamination/cleaning cycle.

Methods: The level of contamination present on disposable endoscopy forceps which come into contact with the lumen of biopsy channels was evaluated. Following observations in endoscopy units, factors influencing protein adsorption inside luminal endoscope channels and the action of current initial cleaning techniques were evaluated using a proteinaceous test soil and very sensitive fluorescence epimicroscopy.

Findings: Disposable endoscope accessories appear to be likely to contribute to the contamination of lumens, and were useful indicators of the amount of proteinaceous soil transiting through the channels of luminal endoscopes. Enzymatic cleaning according to the manufacturer's recommendations and brushing of the channels were ineffective at removing all proteinaceous residues from new endoscope channels after a single contamination. Rinsing immediately after contamination only led to a slight improvement in decontamination outcome.

Conclusion: Limited action of current decontamination procedures and the lack of applicable quality control methods to assess the cleanliness of channels between patients contribute to increasing the risk of cross-infection of potentially harmful micro-organisms and molecules during endoscopy procedures.

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Infection Control of Sheathed Scopes as raised in the CfPP 01-06 guidelines - Issues relating to Vision Sciences (VSI) Flexible Endoscopes

Decontamination of flexible endoscopes: Operational management manual

CONCLUSION

The unique nature of the VSI Endosheath® Technology aseptically fitting sterile sheaths incorporating the working channels on the Vision Sciences non-channelled scopes are different from traditional channelled flexible endoscopes.

- Sheaths fitted over non-channelled scopes are acceptable in the document. This means that Clinicians can be assured of maintaining adherence to the guideline, whilst significantly reducing risk of cross bio-contamination and improving operating efficiency.

What is the CfPP document?

- The CfPP published guideline *'offers best practice guidance on the management and decontamination of flexible endoscopes… '*(14304 – Page 6). *'It supersedes the relevant parts of (HTM) 2030 document*...' Page 7.

- The structure of the document is to divide in to five key areas. Vision Sciences are not a producer of EWD [endoscope washer disinfectors] so these are not discussed except in relation to their use with VSI endoscopes.

14091/14188 (Page 49/50) *looks specifically at non-channelled Nasendoscopes.*

- It states that because of the nature of their use, these non-channelled scopes are manually cleaned with an appropriate medical grade, endoscopic disinfectant.

- Vision Sciences endoscopes are non-channelled so these guidelines apply.
- In addition, as these scopes are non-channelled they also do not require the use of drying cabinets due to the possibility of bacterial contamination on their surface not being replicated in the absence of liquid water.
- It also states that 'as long as direct or indirect recontamination with patient body fluids does not occur, no maximum time of storage before reprocessing can be specified.'

What is the VSI Endosheath® product offering?

- VSI Endoscopes are channel-less flexible endoscopes over which a specific sterile external Endosheath® is fitted
- This provides a sterile insertion tube in contact with the patient rather than a high level disinfected scope provided by the EWD.
- The Endosheath®/endoscope combination means the scope never directly makes contact with the patient.
- The sterile working channel is incorporated in the Endosheath® and the instruments never touch the endoscope
- The risk of cross contamination is vastly reduced because the working channel is disposed of after each case

CfPP guidelines – specific points of relevance

Personnel

*Section 14069***(Page 9)** *states Training should be provided for all staff involved in the decontamination of flexible endoscopes.*

- Genesis Medical provides comprehensive training packages in the form of presentations, supporting materials and training competencies for the users of its products, to ensure they are fully equipped to use the product correctly and in accordance with the validated protocol.
  The trained users are registered and provided with certificates of competence.

Types of EWD and cycles

Section 14073/14165 **(Page 17)** *discusses the use of EWD devices.*

- VSI Endoscopes can be re-processed in an EWD
- Like all manufacturers of endoscopes, VSI would firstly ensure chemical compatibility and functional compatibility with the specific EWD

Reprocessing

*14078/14173***(Page 27)** *points to the use of disposable or re-usable reprocessing accessories, such as cleaning brushes, cleaning tools, endoscope valves and water bottles.*

- The guidelines refer to the need for single use items, which can incur additional cost.
- Reusable items for these purposes also incur on-going costs as functional inventory must be maintained, meaning additional cleaning and maintenance costs.
- VSI scopes have no channels and removes the need for many of these items

Decontamination of Endoscopes

14186 **(Page 41/42)** *discusses the need of the user to follow the manufacturers' guidelines for cleaning.*

- VSI provides this in data form, presentation/visual aids and formal training competency documents
- Conventional channelled endoscopes require essential manual cleaning due to the direct contact with the patient
- VSI endoscope cleaning is prophylactic when used with the Endosheath® in accordance with the manufacturer's guidelines.

14190 **(Page 45/46)** highlights issues in the transportation of HLD cleaned flexible endoscopes

- Additional equipment (transportation trays with a two covers) is required for moving contaminated/decontaminated endoscopes.
- These trays will also require cleaning and decontamination.
- Using VSI endoscopes that do not require the routine use of EWD's removes the issues highlighted here with transportation

Sections 14095 **(Page 56)** *to 14099/14206* **(Page 65)** *look at chemical compatibility with EWD's as well as enzymatic detergents, and flexible endoscopes*

- A full list of compatibility is available upon request
- VSI endoscopes are generally compatible with the commonly used chemicals in the UK.

Traceability

- All VSI Endosheath® packaging have tracking LOT number labels in triplicate on the exterior of the sterile package
- Endosheath® tracking can then be maintained to the highest standards, in addition to any tracking/traceability brought about by periodic use of the EWD system

An example of the Journey of an endoscope through the system

Section 14218 **(Page 76)** *outlines the manual cleaning phase of scope reprocessing,*

- If gross contamination is suspected or the local protocol dictates periodic use of the EWD system then this can be conducted in accordance with CfPP 01-06's guidelines.